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EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/014,842	Applicant(s) RAO ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2007 has been entered.

Claims 1-9 and 21 are pending in the application and are being examined on the merits herein.

The rejection of claims 1-9 and 20 under 35 U.S.C. 112, first paragraph, as adding impermissible new matter, is being withdrawn in view of Applicants' amendments to the claims. However, the amendments to the claims have required the rejections under 35 U.S.C. 112, second paragraph, as set forth below.

Applicants' arguments regarding the rejections of the claims over the prior art have been considered, but are not persuasive. The claims are rejected as set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is not clear what is meant by "11% myristic acid, 9% palmitic acid, 2% stearic acid and 15% stearic acid" as recited in claim 1. Is it intended that the percentages represent the percentage by mol that the component makes up of the interesterified oil, or the percent by weight? As the metes and bounds of the claim cannot be readily determined, it is considered that the claim is indefinite under 35 U.S.C. 112, second paragraph. Claims 2-9 are rejected as being dependent upon a rejected claim.

Claim 9 is further rejected under 35 U.S.C. 112, second paragraph, as having a lack of antecedent basis for the term "n-6 PUFA levels," as recited in the claim. Claim 1, from which claim 9 depends, recites a mol % of the particular n-6 PUFA that is linoleic acid, but does not recite "n-6 PUFA levels" in general, and thus it is not clear what PUFA levels are being referred to in claim 9. Accordingly, claim 9 is considered to be indefinite under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over the article entitled "Modification of Vegetable Oils by Lipase Catalyzed Interesterification" by Kaimal et al (of record.)

Kaimal et al. teaches lipase catalyzed interesterification as a means to modify the fatty acid and glyceride content of common vegetable oils to alleviate drawbacks of these oils (see abstract, in particular.) With regards to coconut oil Kaimal et al. teaches that coconut oil is a saturated fat with lauric acid constituting one of the major fatty acids (see paragraph bridging pages 2-3, in particular.) Kaimal et al. teaches that coconut oil is low in linoleic acid, an essential fatty acid (omega 6 polyunsaturated fatty acid), and thus teaches that it is desirable to remove the C-16 and C-18 saturated acids and incorporate linoleic acid in sufficient amounts to provide essential fatty acid requirements and nutritional quality, as well as to provide medium chain fatty acids that are better absorbed and metabolized (see paragraph bridging page 2-3, in particular.) To this end, Kaimal et al. teaches that lipase catalyzed interesterification can be used to

modify coconut oil by reducing the higher saturated acids with simultaneous incorporation of medium chain fatty acids and linoleic acid (see page 3, left hand columns first through fifth full paragraphs, in particular.)

Kaimal et al. provide examples of the interesterification of coconut oil to improve the nutritional quality of the oil (see paragraph bridging page 7-8 and page 8, in particular.) Kaimal et al. teaches that medium chain fatty acids such as capric and myristic acid are introduced into the coconut oil to reduce the content of higher saturated acids in the oil (see paragraph bridging pages 7-8 and first full paragraph on page 8, in particular.) Kaimal also teaches that in an attempt to incorporate linoleic acid into coconut oil, the coconut oil was interesterified with a mixture of fatty acids including the capric and myristic acids, as well as safflower oil (see page 8, paragraph bridging right and left hand columns, in particular.) Table 17 lists the contents of the resulting interesterified coconut oil, showing an increased linoleic acid (18:2) content over the non-interesterified oil. Kaimal et al. teaches that the coconut oil product may be suitable as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, first full paragraph in left hand column, in particular.)

Accordingly, Kaimal et al. teaches an interesterified coconut oil comprising fatty acids obtained from triglycerides of safflower oil, namely linoleic acid (an omega 5 polyunsaturated fatty acid), and further teaches that the interesterified oil comprises lauric acid because Kaimal et al. teaches that lauric acid is a major fatty acid constituent

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of coconut oil (see paragraph bridging pages 2-3, in particular), and thus teaches providing an interesterified oil comprising linoleic acid and lauric acid, as recited in claims 1 and 21.

Kaimal et al. does not specifically teach the interesterified coconut oil comprising the recited mol % of linoleic acid, lauric acid, myristic acid, palmitic acid, stearic acid, and oleic acid, as recited in claims 1 and 21.

However, Kaimal et al. clearly teaches that fatty acids such as linoleic acid (via interesterification with safflower oil), capric acid and myristic acid can be incorporated into the oil to provide nutritional benefit and can replace the existing fatty acids, especially long chain saturated acids (see paragraph bridging pages 2-3 and pages 7-8 in particular.) Kaimal et al. also teaches that non-interesterified coconut oil itself has a quantity of capric acid fatty acids (10:0) and myristic fatty acids (14:0) and lauric acids (12:0) (see Table 17, in particular.) Kaimal et al. further teaches that long chain saturated fatty acids such as palmitic acid and stearic acid can be removed from the fat and replaced with medium chain length fatty acids during the interesterification process (see paragraph bridging pages 2-3, in particular), and teaches that quantities of palmitic acid (16:0) and stearic acid (18:0) are present in the non-interesterified coconut oil (see Table 17, in particular.) Kaimal et al. also teaches that oleic acid (18:1) is present in the non-interesterified coconut oil (see Table 17, in particular), and teaches that oleic acid can be incorporated via interesterification into oils to reduce the content of unwanted

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fatty acids (see page 4, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of each of the fatty acids provided in the interesterified coconut oil, for example by interesterifying with the fatty acids or replacing the fatty acids in the oil with other fatty acids via interesterification, according to the guidance provided by Kaimal et al, to provide an interesterified oil having desired nutritional properties, such as increased amounts of nutritionally beneficial linoleic acid with regards to the amounts of other acids. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claims 1 and 21 are considered to be obvious over the teachings of Kaimal et al.

It is respectfully pointed out that instant claims 1-9 and 21 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. In the instant case, the claimed product is obvious from the prior art, because the prior art product comprises interesterified coconut oil having fatty acids that

are obtained from the triglycerides of safflower oil, such as linoleic acid. The product thus obtained by the lipase enzyme is deemed to be equivalent to an interesterified coconut oil wherein the fatty acids are obtained from the hydrolysis of triglycerides of safflower oil, as claimed.

Furthermore, it is noted that claims 1 and 21 as written read on interesterifying coconut oil with any of the free fatty acids that are obtained from the hydrolysis of triglycerides of safflower oil, which reads on the interesterification of coconut oil with linoleic acid, a fatty acid that can inherently be obtained in free form from the hydrolysis of triglycerides of safflower oil. Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate linoleic acid into the coconut oil, in an amount and percent by mol as desired, to provide an interesterified coconut oil that is an obvious variant of the product-by-process recited in claim 1. One of ordinary skill in the art would furthermore find it obvious to vary the amount and percent by mol of the linoleic acid incorporated into the coconut oil as well as the percent by mol of other acids incorporated into or removed from the oil, for example to arrive at the percent by mol of linoleic acid recited in claims 1 and 21, and thereby reducing the relative percentage of other fatty acids, such as C16 and C18 saturated fatty acids or even other acids, including lauric acid, with the expectation of providing an interesterified coconut oil having beneficial nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not

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inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 1, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of" is being construed as equivalent to "comprising," absent a clear indication in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03.

While it is not being specifically relied on for the present rejection, it is noted that Applicants teach on page 6 of the instant Specification that the method for the hydrolysis of triglycerides of vegetable oils is known in the art.

Claims 2-3 are directed to compositions wherein the lauric acid provides quick energy for critically ill patients, and is nutritionally beneficial in being hypocholesterolemic and hypotriglyceridemic. It is noted that Kaimal et al. teaches that the interesterified coconut oil can be used as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, right hand column, first full paragraph, in particular.) Furthermore, as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the quick

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energy for critically ill patients and nutritional benefits, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Claims 4 and 6 are directed to compositions wherein the interesterified coconut oil reduces total cholesterol levels in serum by a recited amount, and increases eicosanoid production in immune compromised patients. It is noted that Kaimal et al. teaches that the interesterified coconut oil can be used as a dietary oil for patients with impaired lipid metabolism and for patients under coronary care (see page 8, right hand column, first full paragraph, in particular.) Furthermore, as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the reduction in serum cholesterol level and increased eicosanoid production, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the

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prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 5, Kaimal does not specifically teach that a recovery percentage of the interesterified coconut oil, and thus does not specifically teach a recovery percentage that is in the range of 88-92%, as recited in the claim. However, Kaimal et al. does teach several methods of interesterification of the oils, including by batch stirred reaction and packed-bed continuous reaction (see page 3, right hand column, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to select among the methods taught by Kaimal to obtain a desired recovery percentage of the interesterified coconut oil. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 8, Kaimal et al. teaches an interesterified coconut oil having safflower oil fatty acids and triacylglycerols of coconut oil, as discussed above.

Claim 7 is directed to a composition wherein the interesterified coconut oil has a melting point as claimed and remains a liquid without phase separation. It is noted that as the teachings of Kaimal et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings,

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since the properties, namely the melting point and phase separation properties, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

Regarding claim 9, it is noted that Kaimal teaches an interesterified coconut oil wherein the starting oil is simply coconut oil, and thus has the n-6 PUFA levels that are as claimed or at least are close to those as claimed, and furthermore teaches that linoleic acid can be incorporated into the coconut oil by interesterification, for example via safflower oil, as discussed above. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of linoleic acid and/or safflower oil provided for transesterification with the coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Response to Arguments

Applicant's arguments filed February 22, 2007 have been fully considered but they are not persuasive.

Applicants argue that the Kaimal et al. does not render the composition obvious because Kaimal et al. does not teach the specific mol %'s of the components as claimed. However, as discussed above, Kaimal et al. teaches the desirability of incorporating linoleic acid and other fatty acids into the coconut oil via interesterification to provide nutritional benefits, while removing other fatty acids, such as C16 to C19 saturated fatty acids, and furthermore exemplifies providing the linoleic acid via interesterification with safflower oil. Accordingly, even though Kaimal et al. does not teach the specific mol percentages of linoleic acid and other fatty acids as claimed, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of linoleic acid and other fatty acids provided in the interesterified coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

It is furthermore noted that Kaimal et al. teaches that the fatty acids in coconut oil can be selectively provided or removed according to the desired nutritional and/or cooking benefits, and teaches capric, myristic and oleic acid as acids that are present in non-interesterified coconut oil, and which can optionally be added with fatty acids such as linoleic acid into the coconut oil via interesterification. Kaimal et al. also teaches that long chain saturated fatty acids such as palmitic and stearic acid are present in the unesterified oil, and can be selectively removed. Kaimal et al. also teaches that lauric acid is a component of the unesterified coconut oil, and thus would necessarily be present in the esterified oil in quantities determined by the desired incorporation of linoleic acid and other fatty acids into the oil. Accordingly, even though Kaimal et al. does not teach the specific mol percentages of components as claimed, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the components provided in the interesterified coconut oil, according to the guidance provided by Kaimal et al, to provide an interesterified coconut oil having desired nutritional and/or cooking properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding lauric acid in particular, Applicants argue that the interesterified oils exemplified by Kaimal have, for example, 39.7% lauric acid, whereas Applicants' claim a reduced amount of lauric acid of 17%, and Applicants argue that Kaimal does not

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produce a significantly lower amount of lauric acid than that present in coconut oil. The Examiner notes that the Kaimal et al. does teach examples in which the percent content of lauric acid (12:0) is in fact reduced in the interesterified oil in comparison to the unesterified oil (see Tables 15-18, in particular), and thus in these examples the lauric acid moieties are being replaced (interesterified) by the other desired fatty acid components. Thus it is considered that one of ordinary skill in the art would have found it obvious to vary and/or optimize the amount of lauric acid present in the oil with the respect to a desired amount of linoleic acid, myristic acid, oleic acid, etc, for example by incorporating more linoleic acid into the composition by removing other fatty acids including the lauric acid, with the expectation of achieving an oil having desired nutritional value.

Applicants' further argue that the process of Kaimal et al. increased the percentage of caprylic and capric acid, and decreased oleic acid compared to the unesterified oil, whereas Applicants oil has decreased caprylic and capric acids and increased oleic acid. The Examiner maintains that as Kaimal et al. provides motivation for incorporating into and/or removing the various fatty acids from the coconut oil, and teaches an interesterification process capable of modifying the fatty acid content of the oil, one of ordinary skill in the art would have found it obvious to modify the fatty acid content of the coconut oil via the interesterification process to achieve an interesterified oil having the desired fatty acid content and nutritional benefits.

Applicants furthermore argue that Kaimal et al. follows a different method to generate the product than that claimed, namely the lipase-catalyzed interesterification of coconut oil with safflower oil, whereas the instant claims recite interesterification with free fatty acids obtained from hydrolysis of triglycerides. However, Applicants are respectfully reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113. In the instant case, the product-by-process as claimed is obvious over the product of Kaimal et al, as discussed above.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



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SUPERVISORY PATENT EXAMINER